

Disposable Hemoclip

IFU

(Please read this manual carefully before usage)

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Instruction for Use

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Dear customer:

Thank you for using our products. Please read the manual carefully before you use our products so that you can use and maintain the products accurately.

1. Intended Use

Disposable Hemoclip is the key and common accessory in the treatment and diagnosis of digestive endoscope.

Disposable Hemoclip is indicated for clip placement within the Gastro-intestinal (GI) tract for the purpose of:

- 1) Endoscopic marking,
- 2) Hemostasis for:
 - Mucosal/sub-mucosal defects < 3 cm
 - Bleeding ulcers
 - Arteries < 2 mm
 - Polyps < 1.5 cm in diameter
 - Diverticula in the colon
- 3) Anchoring to affix jejunal feeding tubes to the wall of the small bowel,
- 4) As a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively

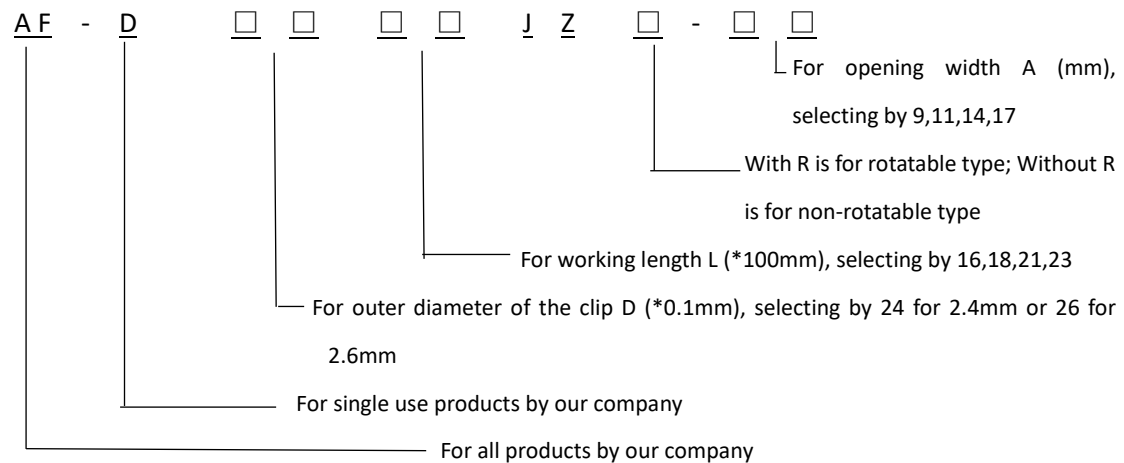
After being applied, the device is excreted in the stools within 30 days in general

situation, and it is a kind of single use device, will be damaged and disinfected after use, and cannot be reused.

2. Models and Specification

1) Disposable Hemoclip consists of the clip (clamp and base), tube and hand holder (it has different models which are suffix with JZ-9, JZ-11, JZ-14, JZ-17, JZR-9, JZR-11, JZR-14 and JZR-17 in different outer diameter and working length for rotatable or non-rotatable type to match with the compatible endoscope), please see figure 1.

2) Models definition as followed:



For example: Disposable Hemoclip, outer diameter of the clip is $\phi 2.4\text{mm}$, working length 1600mm, Rotatable type, opening width is for 11 mm, the model is described as AF-D2416JZR-11. According to the working length we should make sure this kind of model is usually used under the gastroscope. Detailed information should refer to the models list followed.

3) The model and specification of disposable hemoclip. See table 1.

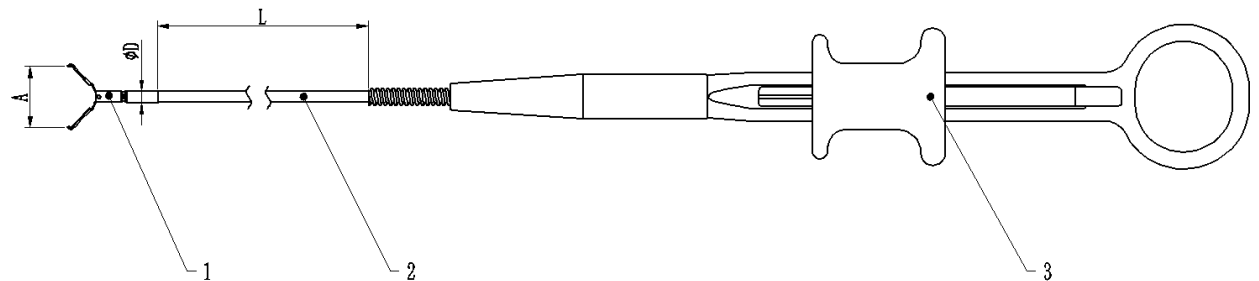


Figure1: Components of the disposable hemoclip

Note: All components of the hemoclip as followed:

- 1, Clip (the clamp with base)
- 2, Tube

- 3, hand holder
4, L: Working Length
5, D: Outer diameter of the clip
6, A: Opening width

Alton (Shanghai) Medical Instruments Co., Ltd. offers 8 different types Suffix with JZ-9, JZ-11, JZ-14, JZ-17, JZR-9, JZR-11, JZR-14 and JZR-17 in different outer diameter and working length for rotatable or non-rotatable type to match with the compatible endoscope. They are all for single use type only.

(See the “Table 1” model list of disposable hemoclip attached)

Table 1 The model list of disposable hemoclip

No.	Outer diameter of the clip	Models	Working length (mm)	Rotatable type or Non-rotatable type	Opening width (mm)	Used for endoscopy
1	Φ2.4 mm	AF-D2416JZ-9	2.4*1600 mm	Non-rotatable	9 mm	Gastroscope
2		AF-D2416JZ-11	2.4*1600 mm	Non-rotatable	11 mm	Gastroscope
3		AF-D2416JZ-14	2.4*1600 mm	Non-rotatable	14 mm	Gastroscope
4		AF-D2416JZ-17	2.4*1600 mm	Non-rotatable	17 mm	Gastroscope
5		AF-D2418JZ-9	2.4*1800 mm	Non-rotatable	9 mm	Gastroscope
6		AF-D2418JZ-11	2.4*1800 mm	Non-rotatable	11 mm	Gastroscope
7		AF-D2418JZ-14	2.4*1800 mm	Non-rotatable	14 mm	Gastroscope
8		AF-D2418JZ-17	2.4*1800 mm	Non-rotatable	17 mm	Gastroscope
9		AF-D2421JZ-9	2.4*2100 mm	Non-rotatable	9 mm	Colonoscopy
10		AF-D2421JZ-11	2.4*2100 mm	Non-rotatable	11 mm	Colonoscopy
11		AF-D2421JZ-14	2.4*2100 mm	Non-rotatable	14 mm	Colonoscopy
12		AF-D2421JZ-17	2.4*2100 mm	Non-rotatable	17 mm	Colonoscopy
13		AF-D2423JZ-9	2.4*2300 mm	Non-rotatable	9 mm	Colonoscopy
14		AF-D2423JZ-11	2.4*2300 mm	Non-rotatable	11 mm	Colonoscopy
15		AF-D2423JZ-14	2.4*2300 mm	Non-rotatable	14 mm	Colonoscopy
16		AF-D2423JZ-17	2.4*2300 mm	Non-rotatable	17 mm	Colonoscopy
17	Φ2.4 mm	AF-D2416JZR-9	2.4*1600 mm	Rotatable	9 mm	Gastroscope
18		AF-D2416JZR-11	2.4*1600 mm	Rotatable	11 mm	Gastroscope
19		AF-D2416JZR-14	2.4*1600 mm	Rotatable	14 mm	Gastroscope
20		AF-D2416JZR-17	2.4*1600 mm	Rotatable	17 mm	Gastroscope
21		AF-D2418JZR-9	2.4*1800 mm	Rotatable	9 mm	Gastroscope
22		AF-D2418JZR-11	2.4*1800 mm	Rotatable	11 mm	Gastroscope
23		AF-D2418JZR-14	2.4*1800 mm	Rotatable	14 mm	Gastroscope
24		AF-D2418JZR-17	2.4*1800 mm	Rotatable	17 mm	Gastroscope
25		AF-D2421JZR-9	2.4*2100 mm	Rotatable	9 mm	Colonoscopy
26		AF-D2421JZR-11	2.4*2100 mm	Rotatable	11 mm	Colonoscopy
27		AF-D2421JZR-14	2.4*2100 mm	Rotatable	14 mm	Colonoscopy
28		AF-D2421JZR-17	2.4*2100 mm	Rotatable	17 mm	Colonoscopy
29		AF-D2420JZR-17	2.4*2000 mm	Rotatable	17 mm	Colonoscopy

30		AF-D2423JZR-9	2.4*2300 mm	Rotatable	9 mm	Colonoscopy	
31		AF-D2423JZR-11	2.4*2300 mm	Rotatable	11 mm	Colonoscopy	
32		AF-D2423JZR-14	2.4*2300 mm	Rotatable	14 mm	Colonoscopy	
33		AF-D2423JZR-17	2.4*2300 mm	Rotatable	17 mm	Colonoscopy	
34	Φ2.6 mm	AF-D2616JZ-9	2.6*1600 mm	Non-rotatable	9 mm	Gastroscope	
35		AF-D2616JZ-11	2.6*1600 mm	Non-rotatable	11 mm	Gastroscope	
36		AF-D2616JZ-14	2.6*1600 mm	Non-rotatable	14 mm	Gastroscope	
37		AF-D2616JZ-17	2.6*1600 mm	Non-rotatable	17 mm	Gastroscope	
38		AF-D2618JZ-9	2.6*1800 mm	Non-rotatable	9 mm	Gastroscope	
39		AF-D2618JZ-11	2.6*1800 mm	Non-rotatable	11 mm	Gastroscope	
40		AF-D2618JZ-14	2.6*1800 mm	Non-rotatable	14 mm	Gastroscope	
41		AF-D2618JZ-17	2.6*1800 mm	Non-rotatable	17 mm	Gastroscope	
42		AF-D2621JZ-9	2.6*2100 mm	Non-rotatable	9 mm	Colonoscopy	
43		AF-D2621JZ-11	2.6*2100 mm	Non-rotatable	11 mm	Colonoscopy	
44		AF-D2621JZ-14	2.6*2100 mm	Non-rotatable	14 mm	Colonoscopy	
45		AF-D2621JZ-17	2.6*2100 mm	Non-rotatable	17 mm	Colonoscopy	
46		AF-D2623JZ-9	2.6*2300 mm	Non-rotatable	9 mm	Colonoscopy	
47		AF-D2623JZ-11	2.6*2300 mm	Non-rotatable	11 mm	Colonoscopy	
48		AF-D2623JZ-14	2.6*2300 mm	Non-rotatable	14 mm	Colonoscopy	
49		AF-D2623JZ-17	2.6*2300 mm	Non-rotatable	17 mm	Colonoscopy	
50		Φ2.6 mm	AF-D2616JZR-9	2.6*1600 mm	Rotatable	9 mm	Gastroscope
51			AF-D2616JZR-11	2.4*1600 mm	Rotatable	11 mm	Gastroscope
52			AF-D2616JZR-14	2.6*1600 mm	Rotatable	14 mm	Gastroscope
53			AF-D2616JZR-17	2.6*1600 mm	Rotatable	17 mm	Gastroscope
54	AF-D2618JZR-9		2.6*1800 mm	Rotatable	9 mm	Gastroscope	
55	AF-D2618JZR-11		2.6*1800 mm	Rotatable	11 mm	Gastroscope	
56	AF-D2618JZR-14		2.6*1800 mm	Rotatable	14 mm	Gastroscope	
57	AF-D2618JZR-17		2.6*1800 mm	Rotatable	17 mm	Gastroscope	
58	AF-D2621JZR-9		2.6*2100 mm	Rotatable	9 mm	Colonoscopy	
59	AF-D2621JZR-11		2.6*2100 mm	Rotatable	11 mm	Colonoscopy	
60	AF-D2621JZR-14		2.6*2100 mm	Rotatable	14 mm	Colonoscopy	
61	AF-D2621JZR-17		2.6*2100 mm	Rotatable	17 mm	Colonoscopy	
62	AF-D2623JZR-9		2.6*2300 mm	Rotatable	9 mm	Colonoscopy	
63	AF-D2623JZR-11		2.6*2300 mm	Rotatable	11 mm	Colonoscopy	
64	AF-D2623JZR-14		2.6*2300 mm	Rotatable	14 mm	Colonoscopy	
65	AF-D2623JZR-17		2.6*2300 mm	Rotatable	17 mm	Colonoscopy	

2.1. Technical Performance Index

- 1) The two sides of disposable hemoclip should be symmetrical, smooth appearance, non-front edge, scar and other defect.
- 2) The stripes and grooves in the collet of disposable hemoclip should be clear, completed and no overflow angle or front edge.

- 3) Surface roughness parameter of disposable hemoclip should be no larger than 0.8 μ m
- 4) Disposable hemoclip should have good clamping performance.

3. Contraindications

- Do not use this device when hemostasis cannot be verified visually with an endoscopic field of view.
- Arteries greater than 2 mm
- Polyps greater than 1.5 cm in diameter
- Mucosal/Submucosal defects greater than 3 cm

3.2 Potential adverse events

- Limited studies indicate that the use of clips in the presence of bacterial contamination may increase or prolong infection.
- Re-bleeding may occur if the clips detach within 24 hours.
- Although rates of occurrence are low, recurrent bleeding, ineffective clipping or endoscopic complications could result in the need for surgery.

4. Warnings, Cautions and Notes

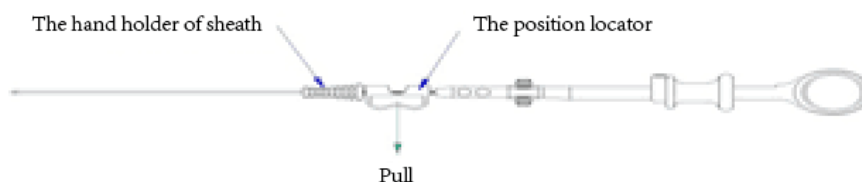
▲ ***Please read the IFU carefully before use, which can help you understand and operate the product serviceably.***

- 1) All users of the disposable hemoclip must be professional medical staff and have related endoscope operation experience.
- 2) This kind of disposable device is only for single use to avoid the device failure and / or spread of disease.
- 3) To be stored in isolation from the patient if don't need use it.
- 4) During the operation process, operator must stop to use it if any accident happened and check the patient to intervene if needed.
- 5) The disposable hemoclip is sterilized before ex-factory by EO. we should use it immediately after opening and don't use it if the single pouch is damaged.
- 6) The clip must be used under endoscope, it can't be used independently, also can't be corrected, repaired or for other use.
- 7) During the operation process, operator must realize to match with the compatible endoscope model, specifications, diameter of working channel to select the hemoclip model to avoid and damage the endoscope.

Such as, model of AF-D2423JZR-11, outer diameter is Φ 2.6mm can be used under the outer diameter of Φ 2.8mm, working length is 2300 mm, opening width of the clip is 11 mm, usually is used in colonoscopy.

5. Check before Use

Refer to the Figure 2 Check before use to check your device before using



- 1) Check for package: inner box including use instruction、 product certificate and product.
- 2) Check for the seal of sterilization bag if tight or not.
- 3) Check the EO sterile signature of the outer single punch to confirm to be sterilized or not.
- 4) The separation or damage of clips from sheath may occur when passing through curved endoscopic channels. Don't use it if the sheath is kinky or clip is damaged.
- 5) Check the device to push or pull the hand holder if smooth and flexible enough. Don't use it if there is any block and should change a new one.

6. Operation steps

- 1) Open the single punch to take the device out.
 - 2) Try to pull the hand holder to close the clip clamp to insert the disposable hemoclip into the working channel to through smoothly and meanwhile pushing the device slowly.
 - 3) According to the visual image by the endoscopy, the operator push and rotate the clip to adjust the position to catch tissue for hemostasis
 - 4) Evaluate the position before release the clip. Don't release the clip before you make the right position if you feel any block, otherwise you can not open and reuse the clip for catching the tissue twice. If you can listen the voice of "KA", and meanwhile you also feel no any strong block that the first connection position of the device was destroyed by your pulling force before, at the situation, you can pull your device to the second connection position until you can listen the voice of "KA" like last time again that means the clip was completely separated.
 - 5) Take the tube sheath out of the working channel after your clip was released.
- Note: don't move the device out of the channel if the clip is open.

7. Cleaning / Sterilization

The disposable hemoclip is delivered sterilized by ETO gas. The disposable

instruments must only be single use. The disposable hemoclip has to be destroyed by the hospital after first use.

8. The method of repairing and maintenance

All instruments are not allowed:

1. To be changed if the sterilization validity date exceed than the date printed on labels
2. To be repaired if for single use device

9. The requirements of working environment

The working environment of clips requires temperature is from 0°C to 40°C, the relative humidity is from 30-85%, air pressure: 50.0-106.0KPa.

10. Storage and transport conditions

- 1) Products cannot be stored and delivered under heavy pressure in order to avoid distortion.
- 2) The storage and transport conditions include:
 - a. Temperature range: 0°C -40 °C;
 - b. Humidity range: 30% - 85%;
 - c. Air pressure: 50.0-106.0KPa
 - d. Stored in clean and dry environment;
 - e. Avoid to be shined directly;
 - f. Deliver by general transport tool, but must avoid by severe shock, vibration, rain and snow splashing.

Do not put any objects on the instrument or its package!
Do not store the instruments near aggressive chemical products!
Do not expose the instruments to direct or indirect sunlight or other ultra-violet rays!

Complaints will not be taken under consideration if the instruments have been stored improperly.








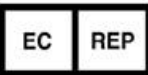





11. The period of sterilization validity is for three years.

12. User

The users of instruments of the **Alton (Shanghai) Medical Instruments Co., LTD** must be specialists in their fields. An appropriate and specific training for preparation, care and maintenance of the flexible instruments is required.

13. MRI Compatibility

16. Symbols

NO.	Description	Symbols on labels
1	CATALOGUE NUMBER	
2	MANUFACTURER	
3	DATE OF MANUFACTURE	
4	USE BY	
5	BATCH CODE	
6	STERILIZED USING ETHYLENE OXIDE	
7	DO NOT REUSE	
8	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	
9	Notified body number	
10	KEEP DRY	
11	KEEP AWAY FROM SUNLIGHT	
12	TEMPERATURE LIMITATION	
13	DO NOT USE IF PACKAGE IS DAMAGED	
14	CONSULT INSTRUCTIONS FOR USE	